

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



In re the application of: Blake Pepinsky *et al.*

Filed: April 11, 2001

Serial No.: 09/832,658

Docket No.: 14937.0059

Issued: November 8, 2005

Patent No.: 6,962,978 B2

For: *POLYMER CONJUGATES OF INTERFERON BETA-1A AND USES*

ATTN: Certificate of Correction Branch
United States Patent and Trademark Office
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Randolph Building
401 Dulany Street
Alexandria, VA 22314

REQUEST FOR EXPEDITED ISSUANCE OF CERTIFICATE OF CORRECTION
PURSUANT TO 37 C.F.R. 1.322

Applicants respectfully request that a Certificate of Correction be issued to correct typographical errors in the claims of the above mentioned patent. The errors were incurred by the U.S. Patent and Trademark Office. A copy of the allowed claims and a copy of the Issue Classification indicating the renumbering of those claims as issued in U.S. Patent No. 6,962,978 are attached at Exhibit A.

With respect to claim 3 (original claim 5), col. 53, line 55 of the '978 patent misspells the word "inlerferon." See attached original claims at p. 2 for support for this correction. With respect to claim 5 (original claim 7), col. 53, line 61 of the '976 patent, the word "ED" is used instead of "ID." See attached original claims at p. 2 for support for this correction. With respect to claim 9 (original claim 11), col. 54, line 59 of the '978 patent omits the word "of" from the claim. See attached original claims at p. 3 for support for this correction. With respect to claim 12 (original claim 15), col. 54, line 66 of the '978 patent, misspells the word "psiologically." See attached original claims at p. 3 for support for this correction. With respect to claim 12 (original claim 15), col. 55, line 2 in the '978 patent, omits a comma from the phrase "alklyene glycol moiety, wherein the physiologically active." See attached original claims at p. 3 for support for this correction.

*Certificate
JAN 12 2009
of Correction*

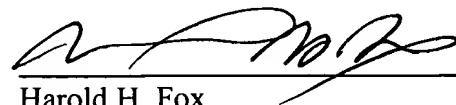
JAN 12 2009

A Certificate of Correction form, PTO/SB/44 is also submitted herewith.

Applicants do not believe that any fees are due with the filing as the error in the claims was incurred by the USPTO. However, should any fees be required by this request, the Commissioner is hereby authorized to charge Deposit Account **19-4293**.

Respectfully submitted,

Date: 1-8-09



Harold H. Fox
Reg. No. 41,498

Steptoe & Johnson LLP
1330 Connecticut Avenue, NW
Washington, DC 20036-1795
Phone: 202-429-3000
Fax: 202-429-3902

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 6,962,978 B2
APPLICATION NO. : 09/832,658
ISSUE DATE : NOVEMBER 8, 2005
INVENTOR(S) : PEPINSKY *et al.*

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 53, line 55, the text "is an inlerferon-beta-1a" should read -- is an interferon-beta-1a --.

Column 53, line 61, the text "SEQ ED NO: 26" should read -- SEQ ID NO: 26 --.

Column 54, line 59, the text "moiety the interferon-beta-1a fusion protein" should read -- moiety of the interferon-beta-1a fusion protein --.

Column 54, line 66, the text "comprising a physiologically active glycosylated interferon-beta-1a" should read -- comprising a physiologically active glycosylated interferon-beta-1a --.

Column 55, line 2, the text "alkylene glycol moiety wherein the physiologically active" should read -- alkylene glycol moiety, wherein the physiologically active --.

MAILING ADDRESS OF SENDER:

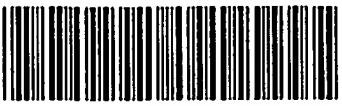
PATENT NO. 6,962,978 B2

Steptoe & Johnson LLP
1330 Connecticut Avenue, NW
Washington DC 20036-1795

JAN 12 2009

Exhibit A

JAN 12 2009

Issue Classification 	Application No.	Applicant(s)	 JAN 08 2009
	09/832,658	PEPIN SKY ET AL.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

ORIGINAL				CROSS REFERENCE(S)							
CLASS	SUBCLASS	CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)								
530	351	530	395	402							
INTERNATIONAL CLASSIFICATION		514	12								
C 0 7 K	14/52	424	85.6.								
C 0 7 K	14/555	930	142								
A 8 1 K	38/21										
	/										
	/										
FOZIA HAMUD 09/29/03 (Assistant Examiner) (Date)				Total Claims Allowed: 24 (Primary Examiner) (Date)							
(Legal Instruments Examiner) (Date)											
				O.G. Print Claim(s)	1				O.G. Print Fig.	none	

<input type="checkbox"/> Claims renumbered in the same order as presented by applicant		<input type="checkbox"/> CPA		<input type="checkbox"/> T.D.		<input type="checkbox"/> R.1.47	
Final	Original	Final	Original	Final	Original	Final	Original
1	1	31	61	91	121	151	181
2	2	32	62	92	122	152	182
		33	63	93	123	153	183
		34	64	94	124	154	184
3	5	35	65	95	125	155	185
4	6	36	66	96	126	156	186
5	7	37	67	97	127	157	187
8	8	38	68	98	128	158	188
9	9	39	69	99	129	159	189
10	10	40	70	100	130	160	190
9	11	6	41	71	101	131	191
10	12	7	42	72	102	132	192
11	13	19	43	73	103	133	193
12	15	20	44	74	104	134	194
16	16	21	45	75	105	135	195
17	17	22	46	76	106	136	196
13	18	23	47	77	107	137	197
14	19	24	48	78	108	138	198
15	20	49	79	109	139	169	199
21	50	51	80	110	140	170	200
16	22	52	81	111	141	171	201
17	23	53	82	112	142	172	202
18	24	54	83	113	143	173	203
25	55	55	84	114	144	174	204
25	56	56	85	115	145	175	205
27	57	57	86	116	146	176	206
28	58	58	87	117	147	177	207
29	59	59	88	118	148	178	208
30	60	60	89	119	149	179	209
				120	150	180	210

(SEQ ID NO:26), A2 (SEQ ID NO:27)), B (B1 (SEQ ID NO:31), B2 (SEQ ID NO:32), C (C1 (SEQ ID NO:33), C2 (SEQ ID NO:34)), D (SEQ ID NO:37), E (SEQ ID NO:40)) and loops (ABI (SEQ ID NO:28), AB2 (SEQ ID NO:29), AB3 (SEQ ID NO:30), CD1 (SEQ ID NO:35), CD2 (SEQ ID NO:36), DE1 (SEQ ID NO:38), DE2 (SEQ ID NO:39)) of interferon-beta-1a (SEQ ID NO: 25). See Example 1

Please replace the pending sequence listing with the enclosed sequence listing.

In the claims:

Please cancel claims 25-40 without prejudice or disclaimer as drawn to a non-elected invention. Please amend claims 1, 5, 7-8, 15, 19 and 22, cancel claims 3-4, 9-10, 14, 16, 17 and 21, add new claims 41-48 and replace the pending claims with the following claims:

1. (Amended) A composition comprising the glycosylated interferon-beta-1a of SEQ ID NO: 25 coupled to a non-naturally-occurring polymer at an N-terminal end of said glycosylated interferon-beta-1a, said polymer comprising a polyalkylene glycol moiety.

2. The composition of claim 1, wherein the polyalkylene moiety is coupled to the interferon -beta by way of a group selected from an aldehyde group, a maleimide group, a vinylsulfone group, a haloacetate group, plurality of histidine residues, a hydrazine group and an aminothiol group.

3. (Amended) The composition of claim 1, wherein the interferon -beta-1a of SEQ ID NO: 25 is an interferon -beta-1a fusion protein.

4. The composition of claim 3, wherein the interferon -beta-1a fusion protein comprises a portion of an immunoglobulin molecule.

5. (Amended) A composition comprising the glycosylated interferon-beta-1a of SEQ ID NO: 26 coupled to a non-naturally-occurring polymer at the N-terminus of said glycosylated interferon-

beta-1a, said polymer comprising a polyalkylene glycol moiety.

8. (Amended) A physiologically active interferon-beta composition comprising a physiologically active interferon-beta-1a comprising the amino acid sequence of SEQ ID NO: 25 coupled to a polymer comprising a polyalkylene glycol moiety, wherein the interferon -beta- 1a is coupled to the polymer at a site on the interferon-beta-1a that is an N- terminal end, wherein the physiologically active interferon -beta 1a and the polyalkylene glycol moiety are arranged such that the physiologically active interferon-beta-1a in the physiologically active interferon -beta composition has an activity at least 2-fold greater relative to physiologically active interferon-beta-1b, when measured by an antiviral assay.

9. The composition of claim 8, wherein the interferon -beta-1a is coupled to the polymer at a site by way of a glycan moiety of the interferon -beta-1a.

10. The composition of claim 8, wherein the interferon-beta-1a is an interferon-beta-1a fusion protein.

11. The composition of claim 10, wherein the interferon-beta-1a fusion protein comprises a portion of an immunoglobulin molecule.

12. (Amended) A physiologically active interferon-beta composition comprising a physiologically active glycosylated interferon-beta-1a comprising the amino acid sequence of SEQ ID NO: 25 N-terminally coupled to a polymer comprising a polyalkylene glycol moiety, wherein the physiologically active interferon-beta-1a and the polyalkylene glycol moiety are arranged such that the physiologically active interferon-beta-1a in the physiologically active interferon-beta composition has equal activity relative to physiologically active interferon-beta lacking said moiety, when measured by an antiviral assay.

13. The composition of claim 12, wherein the interferon -beta is coupled to the polymer at a site by way of a glycan moiety on the interferon-beta.

~~17~~ (Amended) The composition of claim ~~18~~, wherein the interferon-beta-1a is an interferon beta fusion protein.

~~18~~ The composition of claim ~~19~~, wherein the interferon beta fusion protein comprises a portion of an immunoglobulin molecule.

~~19~~ (Amended) A stable, aqueously soluble, conjugated interferon-beta-1a complex comprising a interferon-beta-1a comprising the amino acid sequence of SEQ ID NO: 25 N-terminally coupled to a polyethylene glycol moiety, wherein the interferon-beta-1a is coupled to the polyethylene glycol moiety by a labile bond, wherein the labile bond is cleavable by biochemical hydrolysis and/or proteolysis.

~~20~~ A interferon-beta composition according to claims ~~1, 15 or 22~~, wherein the polymer has a molecular weight of from about 5 to about 40 kilodaltons.

~~21~~ A pharmaceutical composition comprising the interferon-beta composition of claim ~~20~~.

~~22~~ (New) The composition of claim ~~7~~, wherein the glycosylated interferon-beta-1a of SEQ ID NO: 26 is an interferon-beta-1a fusion protein.

~~23~~ (New) The composition of claim ~~41~~, wherein the interferon-beta-1a fusion protein comprises a portion of an immunoglobulin molecule.

~~24~~ (New) A physiologically active interferon-beta composition comprising a physiologically active interferon-beta-1a comprising the amino acid sequence of SEQ ID NO:26 coupled to a non- naturally-occurring polymer at the N-terminus of said glycosylated interferon-beta-1a, said polymer comprising a polyalkylene glycol moiety wherein the physiologically active interferon-beta-1a and the polyalkylene glycol moiety are arranged such that the physiologically active interferon-beta-1a in the physiologically active interferon-beta composition has an activity at

least 2-fold greater relative to physiologically active interferon-beta-1b, when measured by an antiviral assay.

23

~~23~~ (New) The composition of claim ~~13~~, wherein the interferon-beta-1a is an interferon-beta-1a fusion protein.

24

~~24~~ (New) The composition of claim ~~23~~, wherein the interferon-beta-1a fusion protein comprises a portion of an immunoglobulin molecule.

25

~~25~~ (New) A physiologically active interferon-beta composition comprising a physiologically active glycosylated interferon-beta-1a, comprising the amino acid sequence of SEQ ID NO: 25, N-terminally coupled to a polymer comprising a polyalkylene glycol moiety, wherein the physiologically active interferon-beta-1a and the polyalkylene glycol moiety are arranged such that the physiologically active interferon-beta-1a in the physiologically active interferon-beta composition has equal activity relative to physiologically active interferon-beta lacking said moiety, when measured by an antiviral assay.

23

~~23~~ (New) The composition of claim ~~16~~, wherein the interferon-beta-1a is an interferon beta fusion protein.

24

~~23~~ (New) The composition of claim ~~17~~, wherein the interferon beta fusion protein comprises a portion of an immunoglobulin molecule.